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APPLICATION NO. 439	FILING DATE 02/23/00	FIRST NAMED INVENTOR SABEL	ATTORNEY DOCKET NO. B 10644-0001-2
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HM12/0502  
OBLON SPIVAK MCCLELLAND MAIER & NEUSTADT  
1755 JEFFERSON DAVIS HIGHWAY  
FOURTH FLOOR  
ARLINGTON VA 22202

EXAMINER HARTLEY, M
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ART UNIT 1619	PAPER NUMBER 10
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DATE MAILED: 05/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/445,439

Applicant(s)

SABEL ET AL.

Examiner

Michael G. Hartley

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1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2001.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 41-87 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 41-87 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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### **Response to Amendment**

The amendment filed 1/10/2001 has been entered. Claims 1-40 have been canceled. New claims 41-87 have been added.

### **Response to Arguments**

Any previous rejections not reiterated herein have been obviated.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### **Claim Rejections - 35 USC § 112**

Claims 48, 68 and 70 are rejected under 35 U.S.C.112, first paragraph, because the specification, while being enabling for compositions and methods wherein the substance is many of the substances (e.g., drugs) listed in Markush format in these claims, does not reasonably provide enablement for compositions and methods wherein the substance is "transmitter and their respective receptor agonists and receptor antagonists, their respective precursors and metabolites," for the reasons set forth in the office action mailed 7/10/2000.

Applicant's arguments filed 1/10/2001 have been fully considered but they are not persuasive.

Applicant asserts that the amendment obviates this rejection.

This is not found persuasive because the amendment does not in anyway address this rejection. The rejected terminology is still present in the newly added claims.

Claims 41, 50, 48, 54, 55, 68, 70, 72 are rejected under 35 U.S.C.112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons set forth in the office action mailed 7/10/2000.

Applicant's arguments filed 1/10/2001 have been fully considered but they are not persuasive.

Applicant asserts that the amendment obviates this rejection.

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This is not found persuasive because the amendment does not in anyway address these rejections.

The rejected terminology is still present in the newly added claims. For example, claims 41, 54 and 55 still contain the trademark/trade name Genapol®, Bauki®, Pluronic® 68, etc., which were rejected in the previous office action. Also, in newly added claims 48, 68 and 70, the rejected recitation of "transmitter and their respective receptor agonists and receptor antagonists, their respective precursors and metabolites" has not been deleted or clarified. In claims 50 and 72, (which correspond to original claims 8 and 28), the definition of the diagnostic agent as "useful in the diagnosis in nuclear medicine and in radiation therapy" has not been deleted or in anyway amended to clarify.

Applicant's arguments with respect to claims 52, 72, 73 have been considered but are moot in view of the new ground(s) of rejection.

Claims 52, 72 and 73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 52, 72 and 73 recite the limitation "said diagnostic agent" in line 1. There is insufficient antecedent basis for this limitation in the claim.

#### **Claim Rejections - 35 USC § 102**

Claims 41-83 are rejected under 35 U.S.C.102(b) as being anticipated by Hyon (EP 330180), for the reasons set forth in the office action mailed 7/10/2000.

Applicant's arguments filed 1/10/2001 have been fully considered but they are not persuasive.

Applicant asserts that the emulsifying agents used by Hyon are used to stabilize an emulsion and are not incorporated into the nanoparticle.

This is not found persuasive because Hyon clearly discloses that the polymer nanoparticles contain a binder which is in admixture with the polymer, e.g., it is incorporated into the nanoparticle, see page 4, lines 46-54. These materials include some of the same materials instantly claimed, such as polyoxyethylene sorbitan monolaurate, which is polysorbate 85.

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### **Claim Rejections - 35 USC § 103**

Claims 41-87 are rejected under 35 U.S.C.103(a) as being unpatentable over any one of Kreuter (WO 95/22963) or Canal (EP 486959) or Dyatlov (WO 94/15590) or Hyon (EP 330180), or any combination thereof, for the reasons set forth in the office action mailed 7/10/2000.

Applicant's arguments filed 1/10/2001 have been fully considered but they are not persuasive.

Applicant asserts that none of the references teach nanoparticles having the specific stabilizers instantly claimed, and that Hyon teaches the use of stabilizers in an emulsion and not stabilizers which are incorporated into the nanoparticle.

This is not found persuasive because Hyon teaches nanoparticles, which include various stabilizers, such as, polysorbate 85 (polyoxyethylene sorbitan monolaurate), etc., which are within the scope of the instant claims, which also comprise a polymer and a drug. Kreuter, Canal, Dyatlov or Hyon all disclose drug delivery systems, wherein various polymers, stabilizers and drugs may be used interchangeably, as equivalents to obtain desired properties and/or effects. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the stabilizer is "incorporated into the nanoparticles") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

### **Specification**

This application does not contain an abstract of the disclosure as required by 37 CFR1.72(b). An abstract on a separate sheet is required.

This requirement has not been addressed in the response filed 1/10/2001.

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**Conclusion**


No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on (703) 308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
Michael G. Hartley  
Primary Examiner  
Art Unit 1619

MH  
May 1, 2001